Applicants : P. WUTRICH
B. HUET DE BAROCHEZ
V. LEGRAND
C. CASTAN

Serial N°: 10/519,641

Filed : July 15, 2005

Title : Microcapsules for the delayed and controlled release of perindopril

Art Unit : 1615

Examiner : Jeffrey T. Palenik

Honorable Commissioner of Patents
PO BOX 1450
Alexandria, VA 22313

DECLARATION UNDER 37 CFR 1.132

I, Patrick WUTHRICH, a citizen of France, of 937, rue de la Loire 45560 Saint-Denis-en-Val, France, declare and say that :

I am Director of Pharmaceutical Development at the Les Laboratoires Servier, Orleans. My interest of investigation consists of formulation research and developent. I refer to my CV for an extensive overview of my backgrounds and qualifications, of which a copy is attached as Annex I.

I am one of the co-inventors of US Patent Application Serial n° 10/519,641 filed July 15, 2005 concerning " Microcapsules for the delayed and controlled release of perindopril".

I am thoroughly familiar with the above-mentioned patent application and fully support the formulation and pharmacokinetic data contained therein which were performed either by me or under my supervision. I also fully support the conclusions derived and the arguments presented as concerns the therapeutic interest and plasma concentration time curves of the delayed and controlled release form of perindopril described.

The oral pharmaceutical forms disclosed in the present patent application (US Serial n°10/519,641) are used in the treatment of arterial hypertension and heart failure and also have demonstrated original activity in the following pharmacokinetic trials.

The following trials result from the study CL2-5492-004 "Pharmacokinetic-pharmacodynamic relationship and safety assessment after evening administrations of perindopril as small-size particles (type I, 4mg and type II, 5mg) and morning administrations of perindopril as immediate-release tablet (3.338mg)" finalized in October 20, 2005. This study corresponds to a phase II, 2 weeks parallel group study in primary hypertensive patients.

Applicant has enclosed curves of in vivo blood level concentrations of perindopril over time obtained during pharmacokinetic evaluations. Pharmaceutical composition administered to patients during said pharmacokinetic evaluation consists in microcapsules of perindopril covered by at least one coating film comprising at least one hydrophilic polymer A and at least one hydrophobic compound B according to the present invention.

A latent period of about 4 hours is observed wherein the active principle, perindopril, is not released in the plasma and said latent period is followed by a controlled-release period of about 12 hours.

A latent period of about 8 hours is observed wherein the active principle, perindoprilat (active compound liberated in vivo by enzyme action), is not released in the plasma and said latent period is followed by a controlled-release period of about 14-16 hours.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of the title 18 of the United States Code and that such wilful false statements may jeopardize the validity of the application or any patent issued thereon.

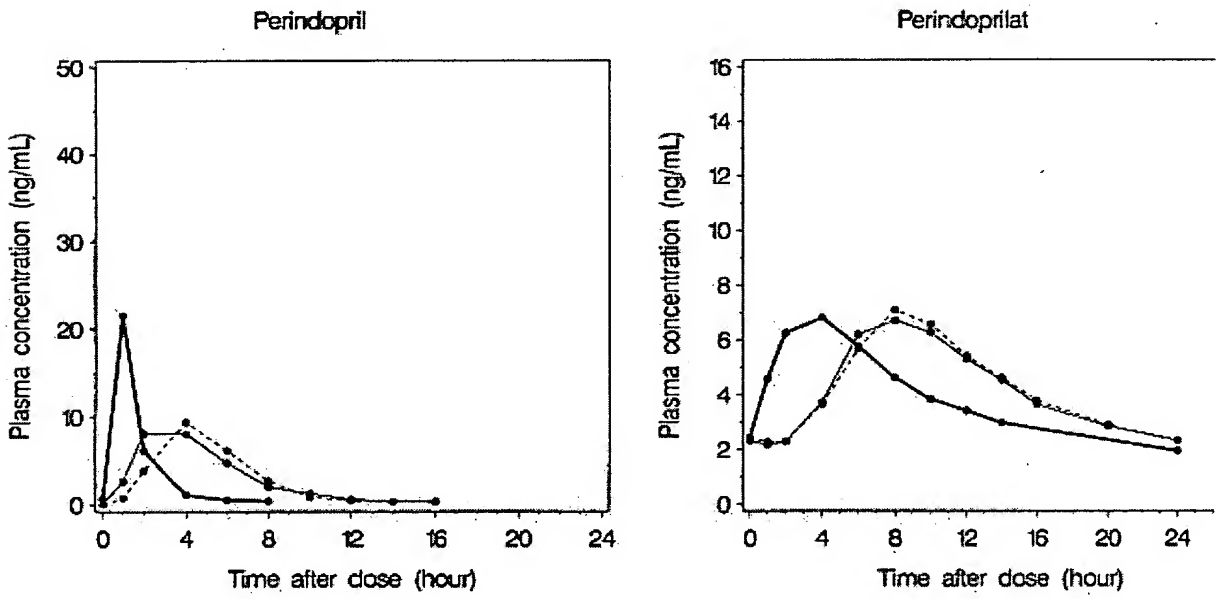
Further declarant sayeth not

Patrick WUTHRICH

Executed at : Orléans
Date : April 24th, 2009

Postal address :
LES LABORATOIRES SERVIER
35 rue de Verdun
92284 SURESNES CEDEX
FRANCE

Mean perindopril and perindoprilat plasma concentration-time curves obtained after repeated morning oral administrations of perindopril as an immediate-release tablet (3.338 mg) or repeated evening oral administrations of perindopril as small-size microparticles (type I 4 mg or type II 5 mg) in hypertensive patients



Full bold line: immediate-release tablet (3.338 mg)
Full line: small-size microparticles (type I, 4 mg)
Dashed line: small-size microparticles (type II, 5 mg)

Secondary pharmacokinetic parameters of perindopril and perindoprilat obtained by non-compartmental analysis following repeated once-a-day oral administrations of perindopril (on D14/D15 or D15/D16, depending on the dosage regimen)

Perindopril			AUCτ (ng.h/mL)				C_{max} (ng/mL)				t_{max} (h)					C_{min} (ng/mL)				t_{lag} (h)				
Form	Dose	N	Mean	s.d.	min	max	Mean	s.d.	min	max	Median	Q1	Q3	min	max	Mean	s.d.	min	max	Median	Q1	Q3	min	max
1	3.338 mg	13	30	16	12	63	22	12	9.0	43	1.0	0.95	1.0	0.020	1.1	BLQ	BLQ	BLQ	BLQ	0	0	0	0	0
2	4 mg	33	36	15	11	67	12	6.1	3.2	28	4.0	3.5	4.3	1.6	8.0	BLQ	BLQ	BLQ	BLQ	1.0	0.50	1.9	0	2.0
2	5 mg	35	40	17	16	98	12	5.7	5.3	34	4.0	3.9	5.9	1.9	8.0	BLQ	BLQ	BLQ	BLQ	0.95	0	1.0	0	2.0

Perindoprilat			AUCτ (ng.h/mL)				C_{max} (ng/mL)				t_{max} (h)					C_{min} (ng/mL)				t_{lag} (h)				
Form	Dose	N	Mean	s.d.	min	max	Mean	s.d.	min	max	Median	Q1	Q3	min	max	Mean	s.d.	min	max	Median	Q1	Q3	min	max
1	3.338 mg	13	91	13	72	112	6.9	1.3	5.0	10	4.0	3.9	4.0	2.0	6.0	1.9	0.39	1.5	2.6	0	0	0	0	0
2	4 mg	33	99	27	55	156	7.2	2.4	3.3	14	8.0	7.0	8.0	5.5	14	2.3	0.70	1.2	4.1	1.1	0.92	1.9	0	4.0
2	5 mg	35	100	25	53	170	7.4	2.5	3.1	15	8.0	6.0	9.9	5.9	14	2.3	0.53	1.4	3.4	1.8	0.92	2.0	0	4.0

Form 1 : Immediate-release **Form 2** : Small-size microparticles

Q1 : 25th percentile **Q3** : 75th percentile

BLQ : below the quantitation limit

CURRICULUM VITAE

Name	WÜTHRICH, Patrick
Date of birth	23 March 1959
Nationality	Swiss
Personal address	937, rue de la Loire 45560 Saint-Denis-en-Val FRANCE Tel. : 33-(0)2-38-77-16-44
Professional address	TECHNOLOGIE SERVIER 25-27, rue Eugène Vignat 45000 ORLEANS Tel. : 33-(0)2-38-23-80-38

EDUCATION

1986-1989	Ph.D. Thesis (Pharmaceutical Formulation Department - University of Geneva - Switzerland)
1984	Pharmacist (University of Geneva - Switzerland)

PROFESSIONAL ACTIVITIES

2008	Director, Head of Pharmaceutical Development - General Manager of the Pharmaceutical Development Center - (SERVIER)
2006-2007	General Manager of the Pharmaceutical Development Center (SERVIER)
1995-2006	Manager of Pharmaceutical Formulation Department (SERVIER)
1992 - 1995	Manager of Pharmaceutical Formulation Department (EUROPEPTIDES - France)
1991	Post-doctoral Researcher (Laboratoires UPSA - France)
1990-1991	International Fellow, Controlled Release & Biomedical Polymers Department,SRI International, Menlo Park, Californie (USA) - Grant of Swiss National Fund for Research
1989-1990	Deputy Pharmacist - Pharmacy of the Geriatrics Hospital in Geneva (Switzerland) Deputy Pharmacist - Pharmacie La Combe in Nyon (Switzerland)
1986 - 1990	Doctoral Deputy - Pharmaceutical Formulation Laboratory - University of Geneva - Member of the National Commission for the Helvetian VII Pharmacopoeia
1984 - 1985	Deputy Pharmacist - Pharmacy Munier SA, Geneva (Switzerland)
1982 – 1983	Deputy Pharmacist - Pharmacy Metro Shopping, Victoria, Vernier, Rossi Geneva (Switzerland)
1981 - 1982	Deputy Pharmacist - In charge of analytical control of raw materials - Pharmaceutical Firm Uhlmann-Eyraud, Geneva (Switzerland)

SCIENTIFIC WORKS

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Title: Supramolecular Organization of S12363-liposomes Prepared with Two Different Remote Loading Processes Article Type: Regular Paper BBA Section: BBA - Biomembranes Corresponding Author: Miss Caroline Chemin All Authors: Caroline Chemin, Ph.D. student; Jean-Manuel PEAN; Claudie BOURGAUX; Georg Pabst; Patrick WUTHRICH; Patrick COUVREUR; Michel OLLIVON Submit Date: Jun 28, 2008

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P. Wüthrich
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P.Wüthrich
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M. L. Leichtnam, H. Rolland, R.H. Guy and P. Wüthrich
"New aerosol transdermal drug delivery system. Effects of formulation parameters upon spray characteristics and permeation enhancement"
Proc. APGI Symposium Skin and Formulation, #43, October 23-24, 2003, Paris

M. L. Leichtnam, R.H. Guy, P. Wüthrich and H. Rolland
"Preformulation and evaluation of a transdermal testosterone spray"
Proc. AAPS November 7-11,2004, Baltimore, USA

E. Allard, J.-M. Péan, H. Rolland, P. Wüthrich
"Solid Dispersion versus Particle Size Reduction to Improve the Dissolution Rate of a Poorly Water-Soluble Drug Substance from Fast-Disintegrating Tablets"
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C. Chemin, J.-M. Pean, C. Bourgaux, H. Rolland, P. Wüthrich, P. Couvreur and M. Ollivon
"Coupled DSC-SWAXS study of interactions between an anticancer drug and sphingomyelin-based liposomes"
ULLA, juillet 2005

C. Chemin, J.-M. Pean, C. Bourgaux, H. Rolland, P. Wüthrich, P. Couvreur and M. Ollivon
"Study of the interaction between an anticancer drug and sphingomyelin-based liposomes"
20th Annual Meeting of the G.T.R.V., 1-2 december 2005, Montpellier, France

C. Chemin, J.-M. Pean, C. Bourgaux, H. Rolland, P. Wüthrich, P. Couvreur and M. Ollivon
"Coupled DSC-SWAXS study of egg sphingomyelin bilayer organization: effect of cholesterol, buffer and temperature"
Biophysical Society, January 18-22, 2006, Salt Lake City, USA

C. Chemin, J.-M. Pean, C. Bourgaux, P. Wüthrich, P. Couvreur and M. Ollivon
"Supramolecular Organization of S12363-liposomes Prepared with two different remote loading processes"
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